

WE CLAIM:

- 1 1. An aqueous solution of risperidone, the aqueous solution comprising:
2 water;
3 a therapeutically effective amount of risperidone or a pharmaceutically acceptable
4 free risperidone base or acid addition salt of risperidone;
5 one or more polyhydric alcohols; and
6 one or more buffering agents configured to maintain the pH in the range of about 3
7 to about 4..
- 1 2. The aqueous solution of claim 1, wherein the addition salt is selected from one or
2 more of salts of risperidone with inorganic acids comprising hydrochloric, hydrobromic,
3 sulfuric, nitric, and phosphoric acids; or organic acids comprising acetic, propanoic,
4 hydroxyacetic, lactic, pyruvic, oxalic, malonic, succinic, maleic, fumaric, malic, tartaric,
5 citric, methane-sulfonic, ethanesulfonic, benzenesulfonic, p-toluenesulfonic, cyclamic,
6 salicylic, p-aminosalicylic, and pamoic acids.
- 1 3. The aqueous solution of claim 1 wherein the one or more polyhydric alcohols
2 comprises one or more of monosaccharides, disaccharides and sugars.
- 1 4. The aqueous solution of claim 3 wherein the monosaccharide comprises one or
2 both of glucose (dextrose) and fructose (levulose).
- 1 5. The aqueous solution of claim 3 wherein the disaccharide comprises one or more
2 of sucrose, lactose, maltose and cellobiose.
- 1 6. The aqueous solution of claim 3 wherein the disaccharide comprises sucrose.
- 1 7. The aqueous solution of claim 3 wherein the sugars comprise one or more of
2 ribose, glycerine, sorbitol, xylitol, maltitol, erythritol, inositol, lactitol monohydrate,
3 propylene glycol, galactose, mannose, xylose, rhamnose, glutaraldehyde, invert sugars,
4 mannitol, polyethylene glycol and glycerol.
- 1 8. The aqueous solution of claim 3 wherein the sugar comprises sorbitol.
- 1 9. The aqueous solution of claim 1 wherein the aqueous solution further comprises an
2 antioxidant.

- 1 10. The aqueous solution of claim 9 wherein the antioxidant comprises one or more of
2 antioxidants, reducing agents and antioxidant synergist.
- 1 11. The aqueous solution of claim 10 wherein the antioxidants comprises one or more
2 of acetylcysteine, alpha tocopherol acetate, d- alpha tocopherol, dl- alpha tocopherol,
3 ascorbyl palmitate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT),
4 cysteine, cysteine hydrochloride and propyl gallate.
- 1 12. The aqueous solution of claim 10 wherein the reducing agent comprises one or
2 more of ascorbic acid, calcium ascorbate, calcium bisulphite, calcium sulphite, ascorbic acid,
3 isoascorbic acid, potassium metabisulphite, sodium ascorbate, sodium bisulphite, sodium metabisulphite,
4 sodium sulphite, sodium thiosulphate and thioglycerol.
- 1 13. The aqueous solution of claim 10 wherein the antioxidant synergist comprises one or more
2 of citric acid, edetic acid (EDTA) and its salts, hydroxyquinoline sulphate, phosphoric acid, sodium citrate
3 and tartaric acid.
- 1 14. The aqueous solution of claim 1 wherein the solution further comprises one or
2 more pharmaceutically acceptable additives.
- 1 15. The aqueous solution of claim 14 wherein the one or more pharmaceutically
2 acceptable additives comprise one or more of preservatives, solubilizers, viscosity
3 enhancing agents, colors and flavors.
- 1 16. The aqueous solution of claim 15 wherein the preservative comprises one or more
2 of benzoic acid, sorbic acid, methyl paraben or salts thereof, propyl paraben or salts
3 thereof, benzyl alcohol and benzylalkonium chloride.
- 1 17. The aqueous solution of claim 1 wherein the buffering agent comprises an acid-
2 base combination.
- 1 18. The aqueous solution of claim 17 wherein the acid comprises one or more of
2 succinic, tartaric, lactic, or citric acid and base is sodium hydroxide or disodium hydrogen
3 phosphate.
- 1 19. The aqueous solution of claim 17 wherein the acid is tartaric acid and base is
2 sodium hydroxide.

- 1 20. The aqueous solution of claim 15 wherein the flavors comprise one or more of
2 vanilla, cherry, raspberry, black currant, strawberry, caramel chocolate, Mint Cool and
3 Fantasy flavors.
- 1 21. A process for the preparation of an aqueous solution, the process comprising:
2 mixing water, a therapeutically effective amount of risperidone or a
3 pharmaceutically acceptable free risperidone base or acid addition salt of risperidone, one
4 or more polyhydric alcohols; and one or more buffering agents configured to maintain the
5 pH in the range of about 3 to about 4.
- 1 22. A method for the management or treatment of the manifestations of psychotic
2 disorders in a mammal, the method comprising administering an aqueous solution
3 comprising water; a therapeutically effective amount of risperidone or a pharmaceutically
4 acceptable free risperidone base or acid addition salt of risperidone; one or more
5 polyhydric alcohols; and one or more buffering agents configured to maintain the pH in
6 the range of about 3 to about 4.